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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/052,758 | 01/18/2002 | Nicholas deBeer | 876635-1 | 1588 |

7590

12/11/2003

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| EXAMINER |
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BARRETT, THOMAS C

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| ART UNIT | PAPER NUMBER |
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3738

DATE MAILED: 12/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/052,758

Applicant(s)

DEBEER ET AL.

Examiner

Thomas C. Barrett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 3, 4, 6, 8, 9, 13, 14, 16, 18, 19, 21 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 5, 7, 10-12, 15, 17, 20 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Species I, sub-species ii, sub-sub-species a in Paper No. 3 is acknowledged.

Claims 3-4, 6, 8-9, 13-14, 16, 18-19 and 21-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 3.

Specification

The use of the trademark "Nitinol" has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 5, 7, 10-12, 15, 17, 20 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 1, 7, 10-11, 17, 20 and 23 each recite the phrase, "biodegradable/biocompatible member". It is unclear whether the Applicant is claiming a member that is biodegradable **and** biocompatible, biodegradable **or** biocompatible, or biodegradable **and/or** biocompatible.

Claims 5 and 15 contain the trademark/trade name "Nitinol". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a type of shape memory alloy and, accordingly, the identification/description is indefinite. See MPEP 2173.05(u).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-2, 5, 7, 11, 12, 15, 17 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Huebsch et al. (5,853,422). Huebsch et al. discloses a catheter delivered septal defect occluder comprising: a tubular frame having parallel slits (col. 3, lines 39-44), made of NITINOL (col. 3, lines 64- col. 4, line 1), with circular biodegradable sheets over each end of the frame (col. 7, lines 44-48). Please note that the portions of the device "exposed to the chambers of the heart" would be circular (FIG. 25). The device can be advanced to the defect from the right side of the heart via a catheter (FIG. 5b) and its proximal end (14) is a releasable attachment means attached to the deployment member (42). Because the biodegradable member covers or **coats** the frame exposed to the chambers of the heart a person of ordinary skill in the art would have recognized the interchangeability of the "coating" shown in the prior art for one of the corresponding "numerous means" for fixing disclosed in the specification (see MPEP 2184).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huebsch et al. (5,853,422) as above in view of Goldstein et al. (6,143,037). Huebsch et al. discloses a septal defect occluder however Huebsch et al. fails to

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disclose the occluder having a galactide and lactide copolymer member covering at least a portion of the umbrella or disc shaped halves. Goldstein et al. teaches a septal defect occluder (col. 31, lines 26-47) having a member (col. 6, lines 33-41) made of a copolymer of glycolic acid and lactic acid (col. 15, lines 37-40) which is useful for targeted local delivery of pharmaceutical agents at a site of medical intervention (col. 1, lines 8-11). It would have been obvious to one of ordinary skill in the art to combine the teaching of a member made of a copolymer of glycolic acid and lactic acid, as taught by Goldstein et al., to a septal defect occluder as per Huebsch et al., for targeted local delivery of pharmaceutical agents at a site of medical intervention. Please Note: a glycolic acid and lactic acid copolymer is a galactide-lactide copolymer as admitted by the Applicant (p 11, lines 7-13).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas C. Barrett whose telephone number is (703) 308-8295. The examiner can normally be reached Tuesday-Friday between 9:00 A.M. and 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703) 308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

A handwritten signature in black ink, appearing to read 'Thomas Barrett', with a stylized flourish at the end.

Thomas Barrett
December 8, 2003